REMARKS

Applicants filed an Amendment in reply to the Final Office Action on March 17, 2009. In the Advisory Action mailed May 22, 2009, the Examiner indicated that the paper of March 17, 2009 had been fully considered and entered. Furthermore, the rejection of claims 1, 3-8 and 36-38 as anticipated by Verma is said to be overcome.

Claims 1, 3-8 and 36-37 remain rejected under 35 USC § 102(a) as anticipated by Bijli et al. (2003) and under 35 USC § 102(b) as anticipated by Bijli et al. (2002).

The Examiner asserts essentially that the claim term "isolated" is interpretable as meaning only that the protein of the invention has been "separated from something else". The Examiner seems to suggest that the 67 kDa protein described in the Bijli references, having been "extracted by EACA and isolated on SDS gel" meets this limitation in the claims. The Examiner further asserts *Thorpe* and other case law for the proposition that merely improving the purity of a claimed composition is not sufficient to establish patentability.

First, Applicants wish to address the issues under *Thorpe* and other cases. The Examiner correctly states the holding of these cases that to establish patentability, the Applicants must show that some unexpected and unique utility or property results from the purification. However, this relates to questions of obviousness, not to questions of anticipation as here. In the present instance, Applicants must only show that the claimed invention is distinct in any manner from what is disclosed in the references.

Even assuming that the Examiner is correct that the 67 kDa proteins disclosed in Bijli (2003) and in Bijli (2002) have in fact been "isolated" (which they have not as explained further below), they have been put through an SDS gel. Such a SDS gel is well known in the art to denature the protein chain and to abolish biological activity of the protein. Applicants wish to strenuously note that no procedure is disclosed by the references for obtaining any protein of having its normal conformation for the proteins as disclosed in Bijli (2003) and in Bijli (2002). Thus, the "isolated" (according to the Examiner) proteins disclosed in the two Bijli references would be considered by one of ordinary skill in the art to not have any biological activity.

In contrast, the proteins as claimed has at least the biological activity of inhibiting proteolytic cleavage of protective antigen of *B. anthracis* ((vi)) as recited in claim 1. Thus, the

claimed protein is distinct from any "isolated" proteins disclosed by the Bijli references and the standing rejections should be withdrawn for at least this reason.

Furthermore, the Examiner's position that the references disclose an "isolated" protein is based upon misinterpretation of the references, as explained further below.

Bijli et al 2003

In this study, the stabilizing effects of different protease inhibitors on *Imperata* extract were studied. The Examiner is advised that EACA (Epsilon amino caproic acid) is a protease inhibitor reagent that is used to stabilize proteins against degradation in protein purification methods. "EACA" is not a technique for protein purification.

As to the Abstract and Figure 2, the Examiner is respectfully requested to read the reference carefully. Review will show that Bijli (2003) does not say anywhere that the protein is isolated or purified. The reference only discloses that a "band" is observed at the relevant molecular weight. Furthermore, this band is not sharp, but rather is broad and diffused therefore is recognized by one of ordinary skill in the art to likely contain a mixture of many proteins. **Figure 2 is a Western blot,** a method used for identification/detection of protein. In this technique, proteins are separated by molecular weight or other parameter and then transferred to an immobilizing membrane. Then, the presence of proteins having immunoreactivity to an antiserum are detected while in place on the membrane. That is, various proteins are visualized, however they are not particularly purified. In this particular instance, proteins reactive with antiserum from allergic patients are visualized.

The Lowry assay described in Bijli et al. 2003 is only a technique for estimating the amount of total protein in a sample. The Examiner should consider that Bijli et al. analyzed a **crude extract** that contains many proteins having molecular weights between 12-110 kDa as shown in figure 1 of the paper.

Bijli et al. 2002

In this paper pollen extract of *I. cylindrica* was prepared by freeze drying or dried at 37°C. The protein profile of the extract was analyzed by SDS-PAGE and allergenicity by immunoblotting in a manner similar to Bijli (2003). The freeze-dried extract from freeze dried was shown to be more potent and showed 33 different IgE-reacting bands. Again, as in Bijli

(2003), a mixture of proteins at 67 kDa is seen in the gel and the immunoblot, evidenced by the fact that the band at this molecular weight is not sharp and is diffused.

At Page 92 column 1, Bijli et al. 2002 has only estimated the amount of the protein of the crude extract, and not of the purified or isolated protein, by the method of Lowry et al.. As explained above, the 67 kDa SDS-PAGE separated band is a mixture of proteins and not a single protein.

Finally, the Examiner should consider that the function of any of the particular proteins within the mixture at 67 kDa is not determined and disclosed in either of the Bijli references. Thus, one of ordinary skill in the art who reads these references would consider that the various biological activities and biochemical properties (i) and (iii) to (viii) recited in claim 1 for the isolated protein of the invention are unexpected (as the Examiner asserts is required for patentability under *In re Thorpe* and others).

In view of the above, Applicants respectfully submit that the present claims define allowable subject matter. Accordingly, the Examiner is respectfully requested to withdraw all rejections and allow the currently pending claims. If the Examiner has any questions or comments, please contact the undersigned at the offices of Birch, Stewart, Kolasch & Birch, LLP, at the telephone number below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

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Respectfully submitted,

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